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| 09/933,438      | 08/20/2001  | Yoshiharu Matahira   | 01503/HG            | 6058             |

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NEW YORK, NY 10017-2023

EXAMINER

GOLLAMUDI, SHARMILA S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 05/07/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/933,438

Applicant(s)

MATAHIRA ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 9-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 9-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Amendment B entered on March 4, 2002.

Claims 1, 3-7, and 9-19 are included in the prosecution of this application.

#### ***Response to Arguments***

Applicant argues that histidine and anserine, carnosine, and valenine are fundamentally different. Further, the applicant argues that the references do not have an antifatigue effect.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that the claims that included histidine were presented in Markush language; therefore although the species (compounds) in the group are not necessarily scientifically equivalent, the species are equivalent for applicant's purpose. Further, the examiner points out that the intended use for a composition, i.e. an antifatigue effect, does not hold patentable weight.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 09020660.**

JP discloses a composition containing anserine (Note abstract).

\*Note the intended use of a composition does not hold patentable weight.

**Claims 1, 3, 6, 7, 9, 12, 14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagrisoli (EP 0449787).**

Nagrisoli discloses a composition containing carnosine (19%) and creatine that is administered to subjects with muscular fatigue (Note example 2). The reference teaches the therapeutic dose of carnosine between 300mg to 5g (pg.2, lines 35-37).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagrisoli (EP 0449787).**

As set forth above, Nagrisoli discloses a composition containing carnosine (19%) and creatine that is administered to subjects with muscular fatigue (Note example 2). The reference teaches the therapeutic dose of carnosine between 300mg to 5g (pg.2, lines 35-37). The reference teaches the use of other dipeptides such as anserine and ophidine (valenine) (pg. 2, lines 18-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use other dipeptides in Nagrisoli's composition as suggested by the reference. One would be motivated to use any of the suggested dipeptides since they contain histidine imidazole ring.

**Claims 4-5, 9-11, 13, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagrisoli (EP 0449787) in view of EP 0652012.**

As set forth above, Nagrisoli discloses a composition containing carnosine (19%) and creatine that is administered to subjects with muscular fatigue (Note example 2). The reference teaches the therapeutic dose of carnosine between 300mg to 5g (pg.2, lines 35-37). The reference teaches the use of other dipeptides such as anserine and ophidine (valenine) (pg. 2, lines 18-21). Nagrisoli teaches the use of sugars (glucose, fructose) in the examples.

Nagrisoli does not teach the use the instant sugar.

EP 0652012 discloses a composition for chronic fatigue syndrome containing of amino acids, sugars (glucose, fructose, and ribose), and calcium in instant amounts (Note examples 1 and 25, claim 6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Nagrisoli and EP since both teach antifatigue compositions. EP teaches the equivalence of the instant sugar with the sugars taught by Nagrisoli; therefore one would be motivated to substitute Nagrisoli's sugars with instant sugar (ribose) with the reasonable expectation of similar results.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

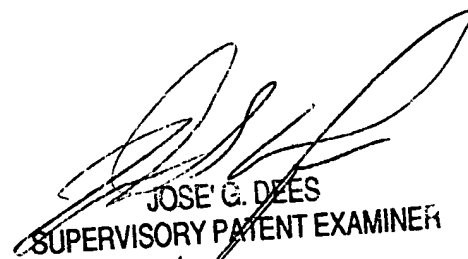
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
1616

SSG  
  
April 24, 2002